GenBio
15222 Avenue of Science, Suite A
San Diego, CA 92128

858.592.9300
FAX 858.592.9400
email genbio@genbio.com

October 27, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: #1352, Guidance for Industry and for FDA Reviewers/Staff, Guidance on Labeling for Laboratory Tests, released on June 24, 1999

Dear Sirs:

As you must understand, changes are always a concern. They may lead to confusion and possible misuse since all must learn new rules. If a change is needed, please be aware that most *in vitro* diagnostic product end users are the clinicians. In most cases, this means the physician is making the patient diagnosis. In some cases, the end user is an auxiliary clinical decision maker (e.g., clinical microbiologist or immunologist) who provides guidance to the physician. It is this person who must understand the FDA's intent. As you may already understand, these end users may not read or use the package insert. Because of this complex relationship, effective implementation to define differences between comparison studies and clinical studies may prove difficult.

I have one suggestion that may be useful. Instead of defining new terms and educating all to understand the new term (e.g., co-positivity, relative sensitivity, etc.), a clear statement may be better. For example the Performance Characteristic section may begin,

"It is probable that this kit will yield similar performance characteristics and provide similar clinical outcome as other products with this same intended use."

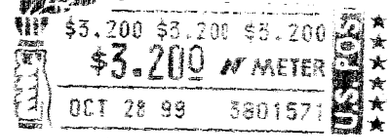
In effect, this is what is demonstrated during the 510(k) clearance process. The term "probable" can be assessed using the indirect method of comparison testing and relative power evaluation. As an alternative, a formula using Bayesian statistics may prove better. If such a formula could be developed, perhaps the probability could be quantified and listed (e.g., "It is probable (85-98%) that this ...").

I do caution that users who want to know the "sensitivity/specificity" of the kit will be able to derive the information. This will possible since the basic comparison information is a required part of any 510(k) notification and therefore must be public information.

I have one other observation. In several cases I have been involved in data compilation and review of "clinical" studies. It is true that these type studies may provide better scientific information that a simple comparison study, but I am not sure that they will always provide better clinical information. Simply because you conclude that a new test is 96% sensitive based on clinical studies does not mean that an older method reporting less or more sensitivity is better or worse. I think that FDA does not want to find itself in the "marketing" business developing labeling that makes one cleared product better than another if both have the same intended use and indications for use.

Sincerely,

Bryan L. Kiehl, Ph.D.
Vice-President



FROM:

GenBio *15222 Avenue of Science, Suite A*
San Diego, California 92128

TO Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and
Management Services
Food and Drug Administratin
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852